



NOV - 3 2000

510(k) SUMMARY

**1.0 Submitter:**

Name: WRP Asia Pacific Sdn Bhd  
Address: Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru Salak Tinggi, 43900 Sepang, Selangor Darul Ehsan, MALAYSIA  
Phone No.: +60 3 8706 1486  
Fax No.: +60 3 8706 1485

Date of Summary Prepared: September 21, 2000

**2.0 Contact Person:**

Name: Mr. Yue Wah, CHOW  
Phone No.: +60 3 8706 1486  
Fax No.: +60 3 8706 1485

**3.0 Name of the device:**

Trade Name: Profeel Powder Free Polymer Coated Neoprene Surgical Glove, Sterile.  
Common Name: Surgical Gloves  
Classification Name: Surgeon's Gloves (per 21 CFR 878.4460)

**4.0 Identification of The Legally Marketed Device:**

Class I Powder Free Synthetic rubber latex Surgeon's gloves, 79KGO, that meets all the requirements of ASTM standard D 3577 - 00 Type 2 and FDA 21 CFR 800.20.

**5.0 Description of The Device:**

The Powder Free Polymer Coated Neoprene Surgical Glove, Sterile meets all the requirements of ASTM standard D 3577 - 00 and FDA 21 CFR 800.20.



## 6.0 Intended Use of the Device:

The Powder Free Polymer Coated Neoprene Surgical Glove, Sterile is made of synthetic rubber latex intended to be worn on the hand of healthcare personnel, operating room personnel and similar personnel to prevent contamination between the healthcare or similar personnel and the patient's body, fluids, waste, or environment.

## 7.0 Summary of The Technological Characteristics of The Device:

The Powder Free Polymer Coated Neoprene Surgical Gloves, Sterile are summarized with the following technological characteristics compared to ASTM or equivalent standards.

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE
Dimensions	ASTM D 3577 - 00	Meets
Physical Properties	ASTM D 3577 - 00	Meets
Freedom from pinholes	ASTM D 3577 - 00 FDA 21 CFR 800.20	Meets
Powder-Free	ASTM D 6124 - 00	Meets 2 mg/glove maximum
Biocompatibility	Primary Skin Irritation in Rabbits	Passes (Not a primary skin irritant)
	Dermal Sensitization	Passes (Not a contact sensitizer)



**8.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data**

The performance test data of the non-clinical tests that support a determination of substantial equivalence is the same as mentioned immediately above.

**9.0 Substantial Equivalent Based on Assessment of Clinical Performance Data**

Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

**10.0 Conclusion**

It can be concluded that the Powder Free Polymer Coated Neoprene Surgical Glove, Sterile will perform according to the glove performance standards referenced in section 7 above and meet ASTM standards, and FDA requirements for water leak test on pinhole AQL. Consequently, this device is substantially equivalent to currently marketed devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Mr. Yue Wah Chow  
Head of Department, QA/RA  
WRP Asia Pacific Sdn Bhd  
Lot 1, Jalan 3, Kawasan Perusahaan  
Bandar Baru Salak Tinggi  
43900 Sepang  
Selangor Darul Ehsan  
MALAYSIA

Re: K003019  
Trade Name: Profeel Powder Free Polymer Coated Neoprene  
Surgical Gloves, Sterile  
Regulatory Class: I  
Product Code: KGO  
Dated: September 21, 2000  
Received: September 27, 2000

Dear Mr. Chow:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

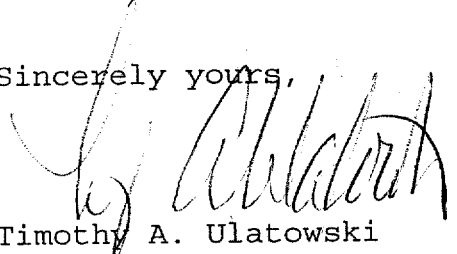
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INDICATIONS FOR USE

Applicant: WRP Asia Pacific Sdn Bhd

510(k) Number (if known): K003019

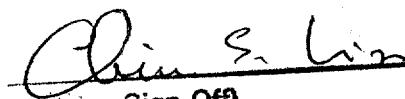
Device Name: PROFEEL POWDER FREE POLYMER COATED  
NEOPRENE SURGICAL GLOVES, STERILE.

Indications For Use:

*natural or*

The surgeon's glove is a device made of ~~synthetic~~ rubber latex intended to be worn by surgeons and/or operating room personnel to protect a surgical wound from contamination.

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K003019

Prescription Use \_\_\_\_\_ OR Over-The-Counter X  
(Per 21 CFR 801.109)